



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,371	03/16/2001	John EN Morten	P277176	9624

909 7590 11/27/2001

PILLSBURY WINTHROP LLP
1600 TYSONS BOULEVARD
MCLEAN, VA 22102

EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
----------	--------------

1655

DATE MAILED: 11/27/2001

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,371

Applicant(s)

MORTEN, JOHN EN

Examiner

Carla Myers

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-4, 6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1655

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-4, 6 and 7 drawn to methods of diagnosis and nucleic acids, classified in Class 435, subclass 6, and Class 536, subclass 23.5.

II. Claim 5, drawn to a computer readable medium, classified in Class 702, subclass 20.

III. Claim 8, drawn to use of an antagonist to prepare a medicant, classification cannot be determined without additional information regarding the structural properties of the antagonist.

IV. Claim 9, drawn to method of treatment using a VCAM-1 antagonist, classification cannot be determined without additional information regarding the structural properties of the antagonist.

V. Claim 10, drawn to a pharmaceutical pack comprising a VCAM-1 antagonist and instructions, classification cannot be determined without additional information regarding the structural properties of the antagonist.

VI. Claim 11, drawn to methods for identifying compounds that effect expression of VCAM-1, classified in Class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant

Art Unit: 1655

case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination has its own distinct identifying characteristics and sequences recited in a database are distinct from physical nucleic acid molecules. Furthermore, the subcombination has separate utility such that the nucleic acid may be used as a probe for diagnostic methods or may be used for the synthesis of proteins.

Inventions I and III and I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the methods of inventions III and IV do not require the nucleic acids of invention I.

Inventions I and V are patentably distinct in structure and physicochemical properties. Invention I is drawn to DNA whereas invention II is drawn to antagonists. Because DNA is composed of a specific nucleotide sequence and antagonists may consist of any type of organic or inorganic molecule, the inventions have different structural and functional properties. Furthermore, the compositions are utilized in different methodologies, such that DNA is utilized in e.g. hybridization assays, whereas the antagonists may be used in methods of treatment.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.

Art Unit: 1655

§ 806.05(h)). In the instant case, the DNA of invention I may be used in a materially different process such as methods of diagnosis or methods for synthesizing proteins.

Inventions II and III, II and IV, II and V and II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the computer readable medium of invention II is not required to practice the methods of inventions III, IV or VI and the computer readable medium of invention II has different functions as compared to the pharmaceutical composition of invention V .

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the methods of inventions III and IV have different method steps and have different objectives, such that the method of invention III results in the generation of a medicant whereas the method of invention IV results in the treatment of an individual.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the pharmaceutical compositions of invention V may be used in

Art Unit: 1655

a materially different process, such as methods of treatment that do not require performing a step of detecting a polymorphism.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the methods of inventions III and VI have different method steps and have different objectives, such that the method of invention III results in the generation of a medicant whereas the method of invention IV results in the identification of a compounds which modulates VCAM-1 expression.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the pharmaceutical compositions of invention V may be used in a materially different process, such as any other treatment method which does not require detecting the presence of a polymorphism prior to administering a pharmaceutical composition.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the methods of inventions IV and VI have different method steps, involve the use of

Art Unit: 1655

different reagents and have different objectives, such that the method of invention IV results in the treatment of an individual and the method invention VI results in the identification of a compounds which modulates VCAM-1 expression.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the pharmaceutical composition of invention V is not required to practice the method of invention VI.

Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-VI require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

During a telephone conversation with Donald Bird on November 5, 2001 a provisional election was made with traverse to prosecute the invention of group I, claims 1-4, 6 and 7. Affirmation of this election must be made by applicant in responding to this Office action. Claims 5, 6, and 13-17 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the

Art Unit: 1655

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

2. The disclosure is objected to because of the following informalities:

Claim 3 recites an improper format for a Markush group, i.e. "method selected from...". The claim should be amended to recite "a method selected from the group consisting of". See MPEP 2173.05(h).

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 6 and 7 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific or well-established utility.

The claims are drawn to methods for diagnosing a nucleotide polymorphism and nucleic acids comprising a polymorphism. The claimed methods and nucleic acids are not supported by either a specific and substantial asserted utility or a well-established utility. The specification teaches that the polymorphisms are present in the promoter region of VCAM-1 and that the polymorphisms alter known transcription factor binding sequences (see, for example, pages 14-15). However, the specification does not teach that an alteration at any of the specified nucleotide positions alters expression of VCAM-1. The specification (pages 6-7) suggests that the disclosed polymorphisms can be used to diagnose disease, or can be used to develop drugs

Art Unit: 1655

for the treatment of diseases or can be used to evaluate the efficacy of therapeutic compounds. However, the specification has not clearly taught an association between the disclosed VCAM-1 polymorphisms and the occurrence of disease. Therefore, it is clear that further research would be required to practice the claimed methods and to use the disclosed polymorphisms because this would require identifying a disease which is correlated with the presence of the VCAM-1 polymorphisms. The use of the claimed method to search for diseases that are correlated with the VCAM-1 polymorphisms constitutes a research use only and does not constitute a "real world" context of use. As stated in *Brenner v. Manson*, 383 U.S. 519 535-536, 148 USPQ 689, 696 (1966) "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". Furthermore, the concept of analyzing a gene for a polymorphism to determine the status of an individual is considered to be a general use and is not considered to be a substantial, specific utility. Accordingly, the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

4. Claims 1-4, 6 and 7 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial, or credible asserted utility or well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Art Unit: 1655

5. Claims 1-4, 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 6 and 7 are indefinite over the recitation of "EMBL ACCESSION NO: M92431" because it is not clear as to what is encompassed by this phrase. The sequences listed in an EMBL database are continuously updated and modified. Therefore, there is no single, constant definition for the sequence presented as EMBL Accession No. M92431. It is suggested that the claims be amended to refer to the position of the polymorphism relative to the start site, to the extent that this is supported by the specification or use a numbering scheme relative to a specific nucleotide sequence provided in a sequence listing.

Claims 1-4, 6 and 7 are indefinite over the recitation of "the positions" because this phrase lacks proper antecedent basis because the claims do not previously refer to positions in the stated EMBL Accession No.

Claims 1-3 are indefinite for failing to recite a positive process step which agrees back with the preamble. The claims are drawn to methods for diagnosing a polymorphism, yet recite a final step of determining the status of a human by reference to a polymorphism in the VCAM-1 gene. Therefore, it is unclear as to whether the claims are intended to be limited to methods for diagnosing a polymorphism or methods for determining the status of a human. It is also unclear as to what is intended to be meant by "diagnosing a polymorphism". For example, it is unclear as to whether this is intended to refer to detecting a polymorphism or to evaluating or further

Art Unit: 1655

characterizing a polymorphism. Furthermore, the claims are indefinite and unclear over the recitation of "status of a human" because the claims do not define what is intended to be meant by "status" and the claims do not clearly set forth how the "status of a human" is determined by "reference" to a polymorphism.

Claims 2 and 3 are indefinite over the recitation of "the single nucleotide polymorphism at ___ is presence of ___" because it is not clear as to what is intended to be meant by this phrase. It is also unclear as to whether the method requires detection of each of the polymorphisms or if the claim intends to only further define the polymorphisms and only one of the polymorphisms is detected in the method.

Claims 6 and 7 are indefinite over the recitation of "capable of detecting" because capability is a latent characteristic and the claims do not set forth the criteria by which to determine capability. That is, it is not clear whether the recited primers and probes have the potential to detect or do in fact detect the VCAM-1 polymorphism. Amendment of the claim to read e.g. "...primer which detects" would obviate this rejection.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 6 and 7 rejected under 35 U.S.C. 102(b) as being anticipated by Iademarco et al (The Journal of Biological Chemistry (1992) 267: 16323-16329).

Art Unit: 1655

Iademarco et al teaches the sequence of the VCAM-1 promoter region (see figure 3) and primers useful for amplifying sequences of the promoter region (pages 16324-16325). Claim 4 has been interpreted as including any nucleic acid of at least 20 nucleotides. Claim 4 recites the phrase "or a complementary strand" but does not state a specific level of complementarity (e.g. 100%, 90%) and thereby includes nucleic acids having any level of sequence complementarity with the stated sequences. Furthermore, the claims require that the nucleic acids comprise a polymorphism, e.g. a "c" but do not clearly define the sequences surrounding the polymorphism. Accordingly, claim 4 reads on the promoter sequences and primers of Iademarco. Claims 6 and 7 are drawn to allele specific primers and probes. However, the claims do not define the allele that the primers and probes are specific to. The primers of Iademarco are considered to be allele specific because they hybridize to an allele of the VCAM-1 gene and are capable of indirectly detecting the stated polymorphisms since they amplify sequences of the promoter region containing these polymorphisms. Furthermore, the promoter sequence disclosed by Iademarco is considered to be an allele specific probe because it hybridizes to a specific allele of VCAM-1 and it can be used to detect polymorphisms in VCAM-1 by, for example, SSCP.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Application/Control Number: 09/787,371


Page 12

Art Unit: 1655

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

November 13, 2001


CARLA J. MYERS
PRIMARY EXAMINER